

Appl. No. 10/706,104  
Atty. Docket No. 9118M  
Amdt. dated February 7, 2006  
Reply to Office Action of November 7, 2005  
Customer No. 27752

REMARKS

Claim Status

Claims 1 - 35 are pending in the present application. No additional claims fee is believed to be due. Claims 1, 18, 28, 32, and 34 have been amended to more specifically define the invention.

Rejection Under 35 USC §112, First Paragraph

The Office Action states that the term "safe and effective" in claims 1, 18, 28, 32, and 34 is a relative term which renders the claims indefinite. Applicants assert that "safe and effect" amount is defined on page 4 of the specification and one having ordinary skill in the art would know what amount of an ingredient would be safe and effective. However, to advance prosecution, Applicants have removed the term "safe and effective" from the claims.

The Office Action states that the term "particulate retentive agent" relates to an extremely large number of possible products and has no distinct meaning in the art. Applicants assert that a retentive agent is clearly defined in the specification on the end of page 5 and beginning of page 6. Applicants have provided a meaning for the term retentive agent through descriptions and examples in the specification. The retentive agent is limited to a Markush group.

Rejection Under 35 USC §102 Over [reference]

Claims 1, 2, 4, 6-10, 12-16, 30, 32, and 34 are rejected under 35 USC 102(a) and (e) as being anticipated by Lawlor US 6,706,256 B2 (hereinafter referred to as "Lawlor"). Before discussing Lawlor, Applicants would like to summarize the present invention for the Examiner. The present invention relates to a non-cariogenic, chewable, solid unit dose compositions comprising a retentive agent and a topical, oral care carrier. The retentive agent is present in amount of from about 1% to about 40% by weight and will hydrate upon exposure to water or saliva. The composition will form an intact hydrated mass to provide a Retention Index of about 1 to about 4.

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Lawlor discloses an oral care composition containing an effective amount of an antibacterial seed or pulp extract from the Citrus or Vitis plan family. The oral care compositions are formulated for use in the oral cavity and intended to treat or prevent oral malodour. Lawlor discloses that the oral composition can be a confectionery composition, such as a chewing gum, hard and low boiled candy carrier, pressed tablets and the like. Lawlor's examples include 12 chewing gums, 2 lozenge, 2 compressed mints, 2 mouthrinses, and 2 dentifrice compositions. None of these compositions are intended to or disclosed as forming an intact hydrated mass with a Retentive Index of from about 1 to about 4. A chewing gum is chewed, a lozenge and mint are sucked, a mouthrinse is swished, and dentifrices are brushed on the teeth and rinsed. There is no disclosure or suggestion that the compositions in Lawlor should be chewed (except for the chewing gum which would not leave a hydrated mass on the tooth surface) for the specific purpose of leaving an intact hydrated mass on the tooth surface. Therefore, Lawlor does not anticipate the present invention as Lawlor does not contain all elements of the present invention as there are no teachings or suggestions that any confectionery composition during its normal use will result in the composition forming an intact hydrated mass on the tooth surface.

For a claim to be anticipated, each and every element of the claim must be present in the prior art reference. It is not sufficient that a person following the disclosure sometimes obtain the result set forth in the [claim], it must invariably happen. *Standard Oil Co. v. Montedison, S.p.A.*, 664 F.2d 356, 372 (3<sup>rd</sup> Cir. 1981). The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Robertson*, 169 F3d 743, (Fed Cir., 1999). Therefore, Lawlor does not anticipate the present invention as there is no specific disclosure to develop a composition with a Retentive Index of from about 1 to about 4 nor is there any disclosure to use a composition with a Retentive Index of about 1 to about 4 in a way that would always result in the composition forming an intact hydrated mass.

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Rejection Under 35 USC §103(a)

Claims 1-17, 18-26, 27, and 28-34 [and Claim 35] have been rejected under 35 USC §103(a) as being unpatentable over Lawlor in view of Aberg et al., WO 88/10110 (hereinafter referred to as Aberg). Applicants respectfully traverse this rejection. The Lawlor reference is discussed above. As Applicants have pointed out, there is no teaching or suggestion in Lawlor to produce or use a composition forming an intact hydrated mass with a Retentive Index of from about 1 to about 4.

Aberg discloses a tooth cleaning and fluoridating tablet. "The tooth cleaning tablet of the intention is designed to form a self-foaming paste when chewed in the mouth. The paste is then swished around the mouth and through the teeth for about 1 to 2 minutes (preferably at least 2 minutes) and then swallowed. This cleans and polishes the tooth surfaces by mechanical action ..." (page 5, second paragraph) Aberg states the purpose is to use mechanical action to clean and polish the tooth surface. Therefore, Aberg teach away from the present invention which forms an intact hydrated mass to provide a Retention Index of about 1 to 4. A composition retained on the tooth surface would not be able to provide the mechanical action taught in Aberg.

Aberg discloses a carbon dioxide producing composition comprise less than about 50% by weight, and preferably less than 25% by weight. Aberg states this is to provide a paste rather than thin slurry. Although Aberg suggests limiting the amount of carbon dioxide producing part of the composition to less than 50%, and preferably less than 25%. Aberg does not teach or suggest a non-effervescent paste. Aberg simply states that it is not desired to have a thin slurry which would not be as effective for mechanical cleaning. Applicants assert that Aberg does not teach or suggest a non effervescent paste. Aberg simply discloses to control the amount of carbon dioxide produced so that the dentifrice slurry will still provide cleaning.

The Office Action states that "One of ordinary skill in the art would have combined the teachings of Lawlor with that of Aberg to make an oral dentifrice tablet that is non-effervescent, chewable, and one that leaves the substantial amount of the composition on the tooth surface." Neither Lawlor nor Aberg teach or suggest forming a chewable, solid unit dose composition which forms an intact hydrated mass to provide a

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Retention Index of about 1 to 4. Neither reference teaches or suggests forming a non-effervescent composition. Lawlor's objective is to treat malodour in the oral cavity and it is not to leave a substantial amount of the composition on the tooth surface. The objective of Aberg is to clean and polish the tooth surfaces by mechanical action and it is not to leave a substantial amount of the composition on the tooth surface. Therefore, one having ordinary skill in the art would not have been motivated by the disclosure in Lawlor in view of Aberg to develop a chewable, solid unit dose composition that forms an intact hydrated mass to provide a Retention Index of about 1 to about 4.

The Office Action also states that one or ordinary skill in the art would have been motivated to combine the teachings of the above cited prior art and expect a successful result in doing so, because the aim of preventive dentistry has been to improve the efficacy of oral hygiene and overall health in mammals (p.7 and 9) and because the drugs used have previously been used for the same function claimed by applicant (p.8). Applicants assert that one having ordinary skill in the art would not have been motivated to combine Lawlor and Aberg. Lawlor's objective is to treat malodour by a antibacterial seed or plant extract from the Citrus or Vitis plant family. The majority of Lawlor's examples are for a chewing gum. Aberg's objective is to clean and polish the teeth and provide fluoride. Aberg's teaching is for a paste that cleans and polishes the teeth which teaches away from an intact hydrated mass. There are vast number of oral care reference in the prior art and there is no motivation to combine a reference preferably for a chewing gum for treating malodour with a tooth cleaning and fluoridating tablet to produce a composition with a Retentive index of from about 1 to about 4. Therefore, one having ordinary skill in the art would not have been motivated by the teachings of Lawlor in view of Aberg to develop the present invention.

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Conclusion

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejections. Early and favorable action in the case is respectfully requested.

This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1-35 is respectfully requested.

Respectfully submitted,

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